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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,433	02/16/2006	Michael Goldberg	817.1013US	9801

23280 7590 01/19/2007  
DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 SEVENTH AVENUE, 14TH FLOOR  
NEW YORK, NY 10018

EXAMINER
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LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/541,433

Applicant(s)

GOLDBERG ET AL.

Examiner

David Lukton

Art Unit

1654

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25, 27-29 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 29 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-22, 27, 28, 31 and 36-39 is/are rejected.
- 7) ☒ Claim(s) 23-25 and 32-34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Pursuant to the directives of the response filed 10/5/06, claims 1, 27, 28, 31, 34-37 have been amended, and claims 26 & 30 cancelled. Claims 1-25, 27-29, 31-39 remain pending.

Applicants' election of Group 1 (claims 1-25, 29, 38, 39, limited to G1) is acknowledged. Also acknowledged are the species elections.

- a) the objective of the elected method is treatment of diabetes;
- b) the elected insulin is recombinant human insulin;
- c) the pharmaceutical formulation contains 4-CNAB and a pharmaceutically acceptable excipient (in addition to the insulin).

. . . . .

Pursuant to the elections, claims 2-4, 29 and 35 are withdrawn from consideration. Claims 1, 5-25, 27, 28, 31-34, 36-39 are examined in this Office action.

✦

Claim 27 is objected to because of a typographical error. In lines 2-3, the following phrase is present: "said ~~orals~~ administration".

✦

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 5-22, 27, 28, 31, 36-39 are rejected under 35 U.S.C. §103 as being unpatentable over Pilarski (USP 7137951) in view of Byrd (USP 7118762) or Moye Sherman (USP 7115663) or Ekwuribe (USP 7084114) or Ekwuribe (USP 7060675).

Pilarski discloses (col 30, line 59) administration of insulin at bedtime. Pilarski does not specify oral administration. Each of the secondary references discloses orally administrable forms of insulin.

Thus, it would have been obvious to use one of the orally administrable forms of insulin for the advantages cited therein.

[The examiner asserts that Pilarski is entitled to the priority date of 10/23/02. However, even if the priority date were 10/22/03, the fact is that the instantly

claimed invention is not described in any of the provisional applications. The provisional applications make reference to “nighttime”, but not “bedtime”].

✦

Claims 1, 5-22, 27, 28, 31, 36-39 are rejected under 35 U.S.C. §103 as being unpatentable over Ekwuribe (USP 7060675).

Ekwuribe discloses (e.g., col 4, line 10; col 4, line 45) orally administrable insulin. Also disclosed (col 11, line 65) is administration at bedtime.

Thus, the claims are rendered obvious.

✦

Claims 1, 5-22, 27, 28, 31, 36-39 are rejected under 35 U.S.C. §103 as being unpatentable over Miller J. L. (*Clinical Pharmacology and Therapeutics* 53(3), 380-4, 1993) in view of (a) Mesiha Mounir S. (*International Journal of Pharmaceutics* 249(1-2), 1-5, 2002) or (b) Hosny Ehab A. (*International Journal of Pharmaceutics* 237(1-2), 71-6, 2002) or (c) Clement Stephen (*Diabetes Technology & Therapeutics* 4(4), 459-66, 2002).

Miller discloses that administering insulin at bedtime is beneficial. Miller does not disclose oral administration of insulin. However, each of the secondary references discloses orally administrable insulin, and the benefits associated therewith.

Accordingly, it would have been obvious to one of ordinary skill to use orally administrable insulin at bedtime.

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Claims 1, 5-22, 27, 28, 31, 36-39 are rejected under 35 U.S.C. §103 as being unpatentable over Yki-Jarvinen H. (*Annals of internal medicine* 130(5), 389-96, 1999) in view of (a) Mesiha Mounir S. (*International Journal of Pharmaceutics* 249(1-2), 1-5, 2002) or (b) Hosny Ehab A. (*International Journal of Pharmaceutics* 237(1-2), 71-6, 2002) or (c) Clement Stephen (*Diabetes Technology & Therapeutics* 4(4), 459-66, 2002).

Yki-Jarvinen discloses that administering insulin at bedtime is beneficial. Yki-Jarvinen does not disclose oral administration of insulin. However, each of the secondary references discloses orally administrable insulin, and the benefits associated therewith.

Accordingly, it would have been obvious to one of ordinary skill to use orally administrable insulin at bedtime.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

*D. Lukton*

DAVID LUKTON, PH.D.  
PRIMARY EXAMINER